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K994231

ATTACHMENT 7

510(K) SUMMARY
FOR THE
SIEMENS INTEGRATED OPERATING SYSTEM (SIOS)

Submitted by:

Siemens Medical Systems, Inc.
186 Wood Avenue South
Iselin, NJ 08830

December 15, 1999

This 510(k) summary of safety and effectiveness information is being submitted in accordance with the requirements of SMDA 1990 and 21 CFR §807.92.

1. Contact Person:

Ms. Malgorzata Stanek
Phone: (732) 321-3950 Fax: (732) 321-4841

2. Device Name and Classification:

Trade Name:	Siemens Integrated Operating System (SIOS)
Classification Name:	Endoscope and/or Accessories
Classification Panel:	General Surgery
CFR Section:	21 CFR § 876.1500
Device Class:	Class II
Product Code:	78KOG

3. Substantial Equivalence:

The Siemens Integrated Operating System is designed to control select medical equipment in the operating room (OR), allow trained medical personnel direct control of the equipment using remote control (i.e., verbal commands, hand input device), and network with hospital information systems (HIS) and picture archival communication systems (PACS).

The package is substantially equivalent to the following devices:

Device Name	Manufacturer	FDA 510(k) Number	FDA Clearance Date
HERMES ™ Operating Room Control Center and Accessories	Computer Motion	K980787	7/31/98
EndoALPHA ™ Integrated Endosurgery System	Olympus	K981993	8/21/98

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4. **Device Description:**
The Siemens Integrated Operating System (SIOS) is a system capable of networking select medical and non-medical equipment in the operating room (OR) and allowing trained medical personnel direct control of the equipment using remote control (i.e. voice command, touch screen console). The device combines a number of individual functional units through a standard interface to a centralized computer control station.

5. **Intended Use of the Device:**
The SIOS product is intended to optimize procedures in the operating room by providing consistent pre-operative, intra-operative and post-operative equipment control, image and data handling, and networking capabilities.

6. **Summary of Technological Characteristics of the Devices Compared to the Predicate:**
The SIOS product is substantially equivalent to HERMES ™ by Computer Motion and EndoALPHA ™ by OLYMPUS. All systems enable remote control of connected devices without changing the original functionality of those devices.

Kathleen Rutherford
Manager, Regulatory Submissions
Siemens Medical Systems, Inc.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

AUG 1 0 2000

Ms. Malgorzata Stanek, RAC
Senior Technical Specialist
Regulatory Submissions
Siemens Medical Corporation
186 Wood Avenue South
Iselin, New Jersey 08830

Re: K994231
Trade Name: Siemens Integrated Operating System (SIOS)
Regulatory Class: II
Product Code: KOG
Dated: May 30, 2000
Received: May 31, 2000

Dear Ms. Stanek:

We have reviewed your Section 510(k) notification of intent to market the device referenced above and we have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (Premarket Approval), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 895. A substantially equivalent determination assumes compliance with the current Good Manufacturing Practice requirement, as set forth in the Quality System Regulation (QS) for Medical Devices: General regulation (21 CFR Part 820) and that, through periodic (QS) inspections, the Food and Drug Administration (FDA) will verify such assumptions. Failure to comply with the GMP regulation may result in regulatory action. In addition, FDA may publish further announcements concerning your device in the Federal Register. Please note: this response to your premarket notification submission does not affect any obligation you might have under sections 531 through 542 of the Act for devices under the Electronic Product Radiation Control provisions, or other Federal laws or regulations.

This letter will allow you to begin marketing your device as described in your 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801 and additionally 809.10 for in vitro diagnostic devices), please contact the Office of Compliance at (301) 594-4595. Additionally, for questions on the promotion and advertising of your device, please contact the Office of Compliance at (301) 594-4639. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR 807.97). Other general information on your responsibilities under the Act may be obtained from the Division of Small Manufacturers Assistance at its toll-free number (800) 638-2041 or (301) 443-6597 or at its internet address "http://www.fda.gov/cdrh/dsmamain.html".

Sincerely yours,

Donna R. Lachman

Celia M. Witten, Ph.D., M.D.
Director
Division of General, Restorative
and Neurological Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

ATTACHMENT 8

INDICATIONS FOR USE

510(k) Number (if known): K994231
Device Name: *Siemens Integrated Operating System (SIOS)*

Indications For Use:

The SIOS product is intended to optimize procedures in the operating room by providing consistent pre-operative, intra-operative and post-operative equipment control, image and data handling, and networking capabilities.

The SIOS product is limited to use with the following products:

(1) Wolf Endocam - 3CCD Endocam 5507,
(2) Wolf Light Source - Auto-CP 5131,
(3) Wolf Insufflator - Laparo CO_2 Pneu 2332, and
(4) Maquet OR Table – ALPHAMAQUET 1150.

(Please do not write below this line - continue on another page if needed)

Concurrence of the CDRH, Office of Device Evaluation (ODE)

Donna R. Lochner.

(Division Sign-Off)
Division of General Restorative Devices
510(k) Number K994231

Prescription Use ✓ OR Over-The-Counter Use _____
(Per 21 CFR 801.109)